REMARKS

Claims 2-3, 6-7, 13-14, 16-17 and 21-28 are pending in the instant application. Claims 2-3, 6-7, 13-14, 16, 17 and 21-28 have been rejected. Claims 21 and 22 have been amended. Claims 27 and 28 have been canceled in light of the amendments to claims 21 and 22. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

Rejection of Claims under 35 U.S.C. 103(a)

Claims 2-3, 6-7, 13-14, 16-17 and 21-28 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,814,032 issued to Hori et al. ("Hori").

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that claim 21 of the instant patent application has been amended to be drawn to a transdermal patch for external use having a backing layer and a pressure-sensitive adhesive layer formed on one surface of the backing layer, consisting essentially of polyisobutylene, a mineral oil and fentanyl as an active ingredient in the pressure-sensitive adhesive layer, contents of polyisobutylene and fentanyl in the pressure-sensitive adhesive layer respectively ranging from 85.0 to

93.0% by mass and 1 to 6% by mass while the content of the mineral oil being from 0.1 to 0.05 parts by mass based on polyisobutylene, wherein the pressure-sensitive adhesive layer does not contain a hydrophilic polymer. Claim 22 of the instant patent application has been amended to be drawn to a transdermal patch for external use having a backing layer and a pressure-sensitive adhesive layer formed on one surface of the backing layer, consisting essentially of polyisobutylene, a mineral oil, a percutaneous absorption enhancer and fentanyl as an active ingredient in the pressure-sensitive adhesive layer, contents of polyisobutylene and fentanyl in the pressure-sensitive adhesive layer respectively ranging from 83.0 to 93.0% by mass and 1 to 6% by mass while the content of the mineral oil being from 0.1 to 0.05 parts by mass based on polyisobutylene, wherein the pressure-sensitive adhesive layer does not contain a hydrophilic polymer.

Support for this amendment can be found in claims 27 and 28, now canceled.

Arguments presented by Applicants in the response filed August 12, 2009 that the Hori Patent requires as an essential component a hydrophilic polymer and therefore cannot render obvious the instant claims which omit the inclusion of this essential elements were determined to be

unpersuasive. Specifically, the Examiner suggests that it is obvious to omit a component if the function of the component is not required or desired. The Examiner states that "[a]s such if the function of water absorption is not required by the transdermal device of the instant claims, than the omission of a hydrophilic polymer would have been an obvious modification."

Applicants respectfully disagree with the Examiner's narrow characterization of the function of this component as it is contrary to the express teachings of the Hori patent. Applicants respectfully direct the Examiner to col. 1 lines 52-64 of the Hori patent wherein it is taught that the inventors discovered by forming the pressure-sensitive adhesive layer containing a drug with at least a specific amount of an elastomer and a specific amount of a hygroscopic material, a tape preparation excellent in both the characteristics of the skin adhesive property and the low skin irritating property at detaching is obtained. Further, at col. 4, lines 24 through 32, Hori teach that the hygroscopic material which is contained in the pressure-sensitive adhesive layer together with the elastomer is a material for preventing the occurrence of cohesive failure . . . without leaving elastomer on the attached surface when detaching the preparation from the attached surface."

Further beginning at line 57 of col. 4, Hori teach that "[i]f the water absorption of the tape preparation is less than 3% . . . the possibility of peeling off and injuring the horny layer is very high, whereby the desired effect of the present invention cannot be obtained." Clear from the teachings of Hori is that they considered the hydrophilic polymer to be essential to the adhesive and low skin irritating properties of their transdermal device. Criticality of this component to the adhesive properties of the transdermal device of the Hori patent is further implied by Comparative Examples 1-3 which did not contain a hydrophilic polymer and which exhibited inferior adhesive properties.

Applicants herein produced a transdermal device without a hydrophilic polymer which retained excellent adhesive properties, a function of the transdermal device clearly taught by the Hori patent to depend upon inclusion of a hydrophilic polymer in their device.

Omission of this required element of the Hori patent while retaining its function of excellent adhesive properties is clearly an indicia of unobviousness of the present invention. See *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966) and MPEP 2144.04.

Further, MPEP 2143.02 is clear; while obviousness does not require absolute predictability, at least some degree of predictability is required. The Hori patent clearly teaches that the success in adhesive properties and decreased irritation of their transdermal patch is based upon inclusion of a hydrophilic polymer. Thus, this reference provides no reasonable expectation of success with respect to a transdermal patch as claimed which does not contain this element and still exhibits excellent adhesive and cohesive properties. Without any reasonable expectation of success, the instant claimed invention cannot be obvious. See MPEP 2143.02.

Further, Applicants have amended the claims to include a content of polyisobutylene ranging from 85.0 to 93.0% and a content of mineral oil ranging from 0.1 to 0.05 parts by mass based on polyisobutylene. As taught in the specification at page 7, lines 2-6 and page 8, lines 3-11, these are critical amounts which enable achieving a sufficient adhesiveness for a long-term administration while avoiding any remains of the adhesive mass on the skin following removal. Criticality of these ranges is further demonstrated by the Comparative Examples. In Comparative Examples 1 and 3, wherein the polyisobutylene concentration is lower than claimed at 70% and the content of mineral oil

is higher than claimed at 28 or 24%, adhesive mass remained on the skin upon removal. In Comparative Example 2 the mineral oil was lower than claimed at 1% and insufficient adhesive properties were observed.

The Hori patent in no way teaches or suggests the criticality of these claimed ranges.

Instead, the Hori patent teaches that the presence of polyisobutylene at 90% by mass resulted in skin irritation and partial peeling (see Comparative Example 1 of Hori patent) and that use of liquid paraffin cannot solve this problem (see Comparative Example 3). These Comparative Examples clearly constitute a teaching away in the Hori patent from the instant claimed invention and rebut any prima facie case of obviousness over the Hori patent. See MPEP 2144.05.

Further, while there may be references to high and low polyisobutylene, mineral oil and fentanyl scattered through various parts of the Hori patent, nowhere does this patent teach the combination of these elements or the criticality of their ratio to adhesive and cohesive properties of a transdermal device. Instead, the lists provided in the Hori patent potentially result in thousands of different combinations of polymers, permeation enhancers and drugs. Demonstration of criticality of these particular components

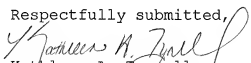
at this ratio in the instant patent application further rebuts any prima facie case of obviousness over the Hori patent. See MPEP 2144.05.

Withdrawal of this rejection under 35 U.S.C. 103(a) is respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of all pending claims is earnestly solicited.

Respectfully submitted,



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